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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,665	11/21/2003	Zairen Sun	ORIGEN-0009-D01	9053
23599	7590	11/27/2006		
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER HADDAD, MAHER M	
			ART UNIT 1644	PAPER NUMBER

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/527,665

Applicant(s)

DE ROMEUF ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 25-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 2, and 25-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant's amendments filed 03/01/2006 and election with traverse of species IL-2 and YB2/0 filed 09/01/2006 are acknowledged.

The traverse is on the ground that the special technical feature of the claimed invention is a correlation between the ability of the Fc region of an antibody to cross-link the CD16 receptor, the biological activity of the antibody and the activation of the effector cells and the production of cytokine; the claimed invention is not taught by Vivier et al. Therefore, the invention has a single general inventive concept and so does not lack unity of invention.

This is not found persuasive because claimed species have no special technical feature that defined in the contribution over the prior art teachings for the reasons of record set forth in the Office Action mailed 06/01/2006 which is hereby reiterated. In addition, Vivier et al. teach a method of measuring the activation of Jurkat with and/or without over-expressing CD16 on cell surface (see entire document, particularly pages 1316-1319). Vivier et al further teach that cross-linking CD16 antigen using antibody on Jurkat cells results in IL-2 production (e.g. see page 1318, column 2 and page 1320, Figure 8). Therefore, the teachings of Vivier et al. meet all the claimed limitations of the instant method. Further, the instant claims encompass any monoclonal and/or polyclonal antibody, therefore, the referenced anti-CD16 antibody meet the claimed limitation of monoclonal and/or polyclonal antibody.

Therefore, the inventions do not have a single general inventive concept and so lack unity of invention.

Consequently, the requirement is still deemed proper and is therefore made FINAL.

Claims 3-24 have been previously canceled.

Claim 28 has been amended.

Claims 1, 2, and 25-36 are pending and currently under consideration as they read on the elected species of IL-2 and YB2/0.

2. Applicant's arguments regarding attempt to amend the instant specification according to the published application rather than the specification as-filed is acknowledged. Applicant argues that because the paragraph numbering system is the PTO's numbering system, the amendments to the specification based on the published application is clear. Applicant further argues that the examiner has not cited a Rule in MPEP for support. Moreover, applicant asserts from his or her own experience that amending to the specification of a patent application based on published application is acceptable.

This is not found persuasive for reasons of record. In addition, it is noted that amendments to the specification, including amendments to a section heading or the title of the invention which are considered for amendment purposes to be an amendment of a paragraph, must be made by submitting an instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a paragraph with one or more replacement paragraphs, or add one or more paragraphs. See 37 CFR 1.121.

In this case, the instant specification, filed 03/11/2005, does not contain paragraph numbers, thus applicant has not submitted instructions which clearly identifies the location in the instant specification as filed for the amendments, compliant with 37 C.F.R. 1.121. It is further noted that the pre-grant publications of patent applications are not under examination by Patent Examiners. If applicant intends to amend pre-grant publication of the instant application, applicant is suggested to use the Electronic Filing System (EFS) to submit pre-grant publication resubmissions for previously filed applications, where the applicant wants an amended, redacted, voluntary, or republication specification to be published rather than the application as originally filed. See MPEP 1730.

Therefore, the amendments to the specification, filed 03/01/2006 is objected to and is not entered.

3. Applicant's drawings, filed 03/01/2006, are acknowledged and have been entered.

4. Applicant's provision of foreign priority documents FRANCE 02/11415 and FRANCE 02/11416 is acknowledged. The certified English translation of the priority application FRANCE 02/11416 appears to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application. However, the English translation of FRANCE 02/11415 has not been provided; thus it is not clear whether the foreign priority document FRANCE 02/11415 provides written description for the instant claims.

5. Applicant's IDS, filed 03/01/2006, is acknowledged and will be addressed in the next Office Action.

6. Upon reconsideration including the addition of new claims 25-36, the following additional Restriction Requirement is set forth herein.

The examiner apologizes for any inconvenience in this matter.

Species Election

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

8. Applicant is required to elect one particular method for measuring the activation of an effector cell belonging to the immune system, wherein the effector cell:

i) may be transformed with monoclonal or polyclonal antibody, **OR**

ii) may not be transformed with monoclonal or polyclonal antibody.

In addition, if applicant elects either (A) or (B), applicant is further required to elect one particular method, wherein the method:

A) does not comprise an ADCC assay, **OR**

B) comprises an ADCC assay.

In addition to the species election above, applicant is further required to elect one particular method, wherein the method is:

a) a method for measuring the activation of an effector cell as recited in claim 1,

b) a method for evaluating the effectiveness of a monoclonal or polyclonal antibody as recited in claim 30,

c) a method for evaluating the ability of a cell to produce an effective monoclonal antibody as recited in claim 31, **OR**

d) a method for evaluating the effectiveness and the integrity of polyclonal antibodies as recited in claim 33.

It is noted that the a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See MPEP 701.

It appears that the preamble of claims 1, 30, 31, and 33 are drawn to different methods, while the body of the claims recite the same or nearly the same process steps, effector cells of the immune system, antigen-antibody, and cytokine production. Applicant is invited to clarify the patentable distinctions between independent claims 1, 30, 31, and 33.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species were found to have no special technical feature that defined the contribution over the prior art of Vivier et al. (International Immunology, 1992, 4:1313-1323. Reference A3 on IDS) (see entire document).

Vivier et al. teach a method of measuring the activation of Jurkat over-expressing CD16 on cell surface (see entire document, particularly pages 1316-1319). Vivier et al further teach that anti-CD16 antibody and anti-CD3 antibody cross-link antigens on Jurkat cells resulting in cell activation and IL-2 production (e.g. see page 1318, column 2 and page 1320, Figure 8).

Since applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g. specific cytokine and specific antibody producing cell) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).


Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
November 17, 2006


PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
TC 1600
11/21/06